



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Lesko, et al.

Appl. No. 09/430,175

Filed: October 29, 1999

For: **Multiple Marker Characterization of
Single Cells**

Confirmation No.: 6875

Art Unit: 1642

Examiner: Canella, Karen A.

Atty. Docket: 1887.0020001/JUK/B-C

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Declaration Under 37 C.F.R. § 1.131

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

We, Paul O. P. Ts'o and Stephen A. Lesko, hereby declare and state that:

1. We are co-inventors of the invention described in U.S. Appl. No. 09/430,175, filed October 29, 1999, entitled *Multiple Marker Characterization of Single Cells*, having a priority date of October 29, 1998.
2. We have reviewed claims 1, 2, 9-25, 28-41, 43-56, 58-61, 64-66, and 68-70 including the amendments to claims 1, 2, 12, 14, 16, 18, 20, 22, 24, 53, 54, 56, 58, and 70 provided in the Amendment and Reply Under 37 C.F.R. § 1.116.
3. We formed a definite and permanent idea of the complete and operative invention as claimed and made the invention as described in the claims of the captioned application in the United States prior to the presentation of the poster by Wang *et al.* at the International Symposium on Biology of Prostate Growth, March 15-18, 1998, at the National Institutes of Health, Bethesda, MD, as evidenced by the following:

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- a. Exhibit A provides pages from the laboratory notebook of Dr. Stephen Lesko, one of the co-inventors, showing an experiment conducted prior to March 15, 1998, in which cells from an epithelial cancer cell line (LnCap cells) were analyzed by fluorescence in situ hybridization (FISH) with an oligodeoxynucleotide probe to chromosome 18, and by immunocytochemistry using an anti-cytokeratin antibody (CK) and an anti-PSMA antibody. The nuclei of the cells were stained with DAPI (blue). The results of the experiment are shown in a color micrograph.
- b. Exhibit B provides pages from the laboratory notebook of Dr. Stephen Lesko, one of the co-inventors, showing an experiment conducted prior to March 15, 1998, in which cells from an epithelial cancer cell line (LnCap cells) were analyzed by fluorescence in situ hybridization (FISH) with an oligodeoxynucleotide probe to chromosome 18, and by immunocytochemistry using an anti-cytokeratin antibody (CK) and an anti-PSMA antibody. The results of the experiment are shown in a color micrograph.
- c. Exhibit C provides pages from the laboratory notebook of Dr. Stephen Lesko, one of the co-inventors, showing an experiment conducted prior to March 15, 1998, in which cells from an epithelial cancer cell line (LnCap cells) were isolated from blood and analyzed by immunocytochemistry using an anti-cytokeratin antibody (CK) and an anti-PSMA antibody. The nuclei of the cells were stained with DAPI (blue). The results of the experiment are shown in a color micrograph.

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4. The attached Exhibits A-C are true and accurate copies of laboratory notebook pages dated before March 15, 1998, recording experiments performed before March 15, 1998. The dates on the laboratory notebook pages have been redacted. From the above, it is clear that we have made the invention as claimed in the captioned application.

5. We have read and understand 37 C.F.R. § 10.18(b) and (c).

9/25/03
Date

Paul O. P. Ts'o
Paul O. P. Ts'o, Ph.D.

9/25/03
Date

Stephen A. Lesko
Stephen A. Lesko, Ph.D.